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Attorneys for Defendant Fresenius Kabi USA, LLC

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

SANOFI-AVENTIS U.S. LLC, AVENTIS : Civil Action No.: 14-7869 (MAS)(LHG)
PHARMA S.A., and SANOFI, :
:
Plaintiffs, :
:
v. :
:
FRESENIUS KABI USA, LLC, :
:
Defendant. :
:

**ANSWER AND COUNTERCLAIMS
OF DEFENDANT
FRESENIUS KABI USA, LLC**

Defendant Fresenius Kabi USA, LLC (“Fresenius”), by and through its counsel, hereby

responds to the Complaint filed by Plaintiffs Sanofi-Aventis U.S. LLC (“Sanofi U.S.”); Aventis Pharma S.A. (“Aventis”); and Sanofi (collectively, “Plaintiffs”) and asserts defenses and counterclaims. This answer is based on Fresenius’s knowledge as to its own activities, and upon information and belief as to the activities of others. The numbered paragraphs below correspond to the numbered paragraphs in Plaintiffs’ Complaint. To the extent not specifically admitted herein, the allegations of the Complaint are denied.

THE PARTIES

1. Upon information and belief, Fresenius admits that Sanofi U.S. is a company organized and existing under the laws of the State of Delaware, having commercial headquarters at 55 Corporate Drive, Bridgewater, New Jersey 08807. Fresenius lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations in Paragraph 1 and therefore denies the same.

2. Upon information and belief, Fresenius admits that Aventis is a corporation organized and existing under the laws of France, having its principal place of business at 20 avenue Raymond Aron, 92160 Antony, France.

3. Upon information and belief, Fresenius admits that Sanofi is a corporation organized and existing under the laws of France, having its principal place of business at 54 rue La Boétie, 75008 Paris, France.

4. Fresenius lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations in Paragraph 4 and therefore denies them.

5. Fresenius admits the allegations in Paragraph 5.

6. Fresenius admits that it filed New Drug Application (“NDA”) No. 207937 with the U.S. Food and Drug Administration (“FDA”), concerning a proposed Cabazitaxel Injection 20

mg/mL (60 mg/3 mL) drug product (“the Fresenius NDA Product”). Fresenius denies the remaining allegations in Paragraph 6.

JURISDICTION AND VENUE

7. Fresenius admits that the Complaint purports to state a claim that arises under the patent laws of the United States of America. Fresenius admits that this Court has jurisdiction over the subject matter of this action. Fresenius denies that Plaintiffs are entitled to any relief.

8. Fresenius denies that this Court has personal jurisdiction over it, whether by general or specific jurisdiction, and observes that Plaintiffs filed a Complaint in the District of Delaware. For the purposes of this litigation only, however, Fresenius will not contest personal jurisdiction.

9. Fresenius admits that Fresenius’s website states the specifically quoted language, but makes no admission with respect to the context of the quoted content. To the extent there are any remaining allegations in Paragraph 9, Fresenius denies them.

10. Fresenius admits that in 2008, it acquired APP Pharmaceuticals, LLC. Fresenius admits that APP Pharmaceuticals, LLC was a pharmaceutical company, and that it maintained a corporate agent at 830 Bear Tavern Road, West Trenton, New Jersey 08628. Fresenius admits that APP Pharmaceuticals, LLC changed its name to Fresenius Kabi USA, LLC. Fresenius admits that Fresenius’s website states the specifically quoted language, but makes no admission with respect to the context of the quoted content. To the extent there are any remaining allegations in Paragraph 10, Fresenius denies them.

11. Fresenius admits that in 2012, it acquired Fenwal Inc. Fresenius admits that Fenwal Inc. is a business entity registered with the New Jersey Department of Treasury, and that Fenwal Inc. maintains a corporate agent for service of process at 830 Bear Tavern Road, West

Trenton, New Jersey 08628. To the extent there are any remaining allegations in Paragraph 11, Fresenius denies them.

12. Fresenius admits that it manufactures and sells drug products. Fresenius further admits that it holds an active wholesale drug and medical device license for the State of New Jersey under License No. 5003710. To the extent there are any remaining allegations in Paragraph 12, Fresenius denies them.

13. Fresenius denies the allegations in Paragraph 13.

14. Fresenius lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 14 and therefore denies them.

15. Fresenius lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 15 and therefore denies them.

16. Fresenius lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 16 and therefore denies them.

17. Fresenius admits that it has previously been sued and asserted counterclaims in this judicial District. Fresenius denies any remaining allegations in Paragraph 17.

18. Fresenius denies the allegations in Paragraph 18.

19. Fresenius lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 19 and therefore denies them.

20. Fresenius lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 20 and therefore denies them.

21. Paragraph 21 contains conclusions of law for which no response is required. To the extent that an answer is required, Fresenius does not contest venue for this particular action.

THE PATENTS-IN-SUIT

22. Upon information and belief, Fresenius admits that Sanofi Aventis U.S. is identified in the electronic version of the FDA's publication *Approved Drug Products with Therapeutic Equivalence Evaluations* ("the Orange Book") as the holder of NDA No. 201023. Upon information and belief, Fresenius further admits that the JEV-TANA prescribing information states that it is "indicated in combination with prednisone for treatment of patients with hormone-refractory metastatic prostate cancer previously treated with a docetaxel-containing treatment regimen." Fresenius lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations in Paragraph 22 and therefore denies them.

23. Fresenius admits that the face of the '170 patent indicates that its title is "Taxoids, Their Preparation And Pharmaceutical Compositions Containing Them" and that the face of the '170 patent indicates that it issued on December 8, 1998. Fresenius further admits that the Orange Book lists the '170 patent as purportedly associated with NDA No. 201023. Fresenius denies the remaining allegations in Paragraph 23.

24. Fresenius lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 24 and therefore denies them.

25. Fresenius admits that the face of the '907 patent indicates that its title is "Acetone Solvate of Dimethoxy Docetaxel and its Process of Preparation" and that the face of the '907 patent indicates that it issued on July 10, 2007. Fresenius further admits that the Orange Book lists the '907 patent as purportedly associated with NDA No. 201023. Fresenius denies the remaining allegations in Paragraph 25.

26. Fresenius lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 26 and therefore denies them.

CLAIMS FOR RELIEF – ALLEGED PATENT INFRINGEMENT

27. Fresenius admits that it submitted a 505(b)(2) application to the FDA seeking approval to manufacture and sell the Fresenius NDA Product.

28. Fresenius admits that its 505(b)(2) application to the FDA seeks approval for the Fresenius NDA Product in combination with prednisone for treatment of patients with hormone-refractory metastatic prostate cancer previously treated with a docetaxel-containing treatment regimen.

29. Fresenius admits that it submitted a 505(b)(2) application to the FDA seeking approval to manufacture and sell the Fresenius NDA Product. Fresenius lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations of Paragraph 29 and therefore denies them.

30. Fresenius admits that in a letter dated November 3, 2014, Fresenius notified Sanofi Aventis U.S. that it had submitted a 505(b)(2) application to the FDA seeking approval to engage in commercial manufacture, use and sale of the Fresenius NDA Product prior to the expiration of the '170 and '907 patents. Fresenius lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations in Paragraph 30 and therefore denies them.

31. Fresenius admits that in a letter dated November 3, 2014, Fresenius notified Sanofi Aventis U.S. that its 505(b)(2) application contained a Paragraph IV certification stating that the '170 and '907 patents are invalid, unenforceable and/or will not be infringed by the manufacture, use or sale of the Fresenius NDA Product.

32. Fresenius admits that its 505(b)(2) application refers to NDA No. 201203.

Fresenius lacks knowledge or information sufficient to form about the truth of the remaining allegations of Paragraph 32 and therefore denies them.

COUNT I

ALLEGED INFRINGEMENT OF U.S. PATENT NO. 5,847,170

33. Fresenius incorporates by reference its responses to Paragraphs 1-32 as if fully set forth herein.

34. Paragraph 34 states conclusions of law to which no response is required from Fresenius. Fresenius denies the remaining allegations in Paragraph 34.

35. Fresenius denies the allegations in Paragraph 35.

36. Fresenius denies the allegations in Paragraph 36.

37. Fresenius denies the allegations in Paragraph 37.

COUNT II

ALLEGED INFRINGEMENT OF U.S. PATENT NO. 7,241,907

38. Fresenius incorporates by reference its responses to Paragraphs 1-37 as if fully set forth herein.

39. Paragraph 39 states conclusions of law to which no response is required from Fresenius. Fresenius denies the remaining allegations in Paragraph 39.

40. Fresenius denies the allegations in Paragraph 40.

41. Fresenius denies the allegations in Paragraph 41.

42. Fresenius denies the allegations in Paragraph 42.

PRAYER FOR RELIEF

43. Fresenius denies each and every allegation in the Complaint not expressly admitted above.

44. Fresenius denies that Plaintiffs are entitled to any of the relief requested in Plaintiffs' Prayer for Relief, including paragraphs A through L of the Prayer for Relief.

DEFENSES

45. Fresenius, without prejudice to the denials set forth in this Answer, allege the following defenses to the allegations in the Complaint. Fresenius reserves the right to supplement this Answer, including the right to assert additional defenses, as more information is learned through discovery.

FIRST DEFENSE
(Noninfringement of the '170 patent)

46. The manufacture, use, offer for sale, sale, marketing, distribution, or importation of the Fresenius NDA product does not and will not infringe any valid and enforceable claim of the '170 patent.

SECOND DEFENSE
(Invalidity of the '170 patent)

47. Each and every claim of the '170 patent is invalid for failure to comply with the requirements of patentability including those requirements set forth in 35 U.S.C. §§ 101 *et seq.*, including 35 U.S.C. §§ 101, 102, 103, 112 or 116, or for obviousness-type double patenting.

THIRD DEFENSE
(Noninfringement of the '907 patent)

48. The manufacture, use, offer for sale, sale, marketing, distribution, or importation of the Fresenius NDA product does not and will not infringe any valid and enforceable claim of the '907 patent.

FOURTH DEFENSE
(Invalidity of the '907 patent)

49. Each and every claim of the '907 patent is invalid for failure to comply with the requirements of patentability including those requirements set forth in 35 U.S.C. §§ 101 *et seq.*, including 35 U.S.C. §§ 101, 102, 103, 112 or 116, or for obviousness-type double patenting.

COUNTERCLAIMS FOR DECLARATORY JUDGMENT

Fresenius, for its counterclaims against Plaintiffs, alleges as follows:

THE PARTIES

1. Counterclaimant Fresenius is a corporation organized and existing under the laws of Delaware, with corporate headquarters at Three Corporate Drive, Lake Zurich, Illinois 60047.

2. Upon information and belief, Plaintiff-Counterdefendant Sanofi Aventis U.S. is a company organized and existing under the laws of the State of Delaware, having commercial headquarters at 55 Corporate Drive, Bridgewater, New Jersey 08807.

3. Upon information and belief, Plaintiff-Counterdefendant Aventis is a corporation organized and existing under the laws of France, having its principal place of business at 20 avenue Raymond Aron, 92160 Antony, France.

4. Upon information and belief, Plaintiff-Counterdefendant Sanofi is a corporation organized and existing under the laws of France, having its principal place of business at 54 rue La Boétie, 75008 Paris, France.

JURISDICTION AND VENUE

5. This is a declaratory judgment action arising under the patent laws of the United States, Title 35 of the United States Code. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a). The requested relief is authorized by the Declaratory Judgment Act, 28 U.S.C. §§ 2201, and 2202.

6. This Court has personal jurisdiction over each Sanofi Aventis U.S., Aventis, and Sanofi because they have subjected themselves to the jurisdiction of this Court by filing the Complaint in this action. In addition, this Court has personal jurisdiction over Sanofi Aventis U.S. because its principal place of business is in New Jersey, making it at home in New Jersey.

7. Venue is proper in this Court under 28 U.S.C. §§ 1391 and 1400(b) and by Counterclaim-Defendants' choice of forum in filing its Complaint against Fresenius.

8. As a consequence of Plaintiffs/Counterclaim-Defendants' Complaint against Fresenius, there now is an actual, substantial, continuing and justiciable controversy between the parties as to the infringement, validity and enforceability of U.S. Patent No. 5,847,170 ("the '170 patent") and U.S. Patent No. 7,241,907 ("the '907 patent").

STATEMENT OF FACTS

9. The face of the '170 patent indicates that its title is "Taxoids, Their Preparation And Pharmaceutical Compositions Containing Them" and it issued on December 8, 1998. The '170 patent lists Hervé Bouchard, Jean-Dominique Bourzat, and Alain Commerçon as inventors, and Rhône-Poulenc Rorer, S.A. as the assignee.

10. The face of the '907 patent indicates that its title is "Acetone Solvate of Dimethoxy Docetaxel and its Process of Preparation" and it issued on July 10, 2007. The '907 patent lists Eric Didier and Marc-Antoine Perrin as inventors, and Aventis Pharma S.A. as the assignee.

11. Plaintiffs have caused the patents-in-suit to be listed in the Orange Book for Jevtana.

12. Fresenius has submitted NDA No. 207937 with the FDA concerning its proposed Cabazitaxel drug product ("the Fresenius NDA Product").

13. Fresenius notified Plaintiffs/Counterclaim Defendants in a letter dated November 3, 2014 (the “Notice Letter”) that it had submitted NDA No. 207937 to the FDA, related to the Fresenius NDA product.

14. In Fresenius’s Notice Letter, Fresenius stated that its NDA included Paragraph IV certifications with respect to the patents-in-suit, alleging that the ’170 and ’907 patents are invalid, unenforceable and/or will not be infringed by the commercial manufacture, use, offer for sale or sale of the Fresenius NDA Product.

15. On December 17, 2014, Plaintiffs/Counterclaim Defendants filed the Complaint, asserting infringement of the patents-in-suit.

COUNT I
**(Declaratory Judgment of Non-Infringement of the ’170 Patent
by the Fresenius NDA Product)**

16. Fresenius incorporates by reference the preceding Counterclaim paragraphs 1 to 15 as if fully set forth herein.

17. The manufacture, use, offer for sale, sale, or importation of the Fresenius NDA Product does not and will not infringe, directly or indirectly, any valid and enforceable claim of the ’170 patent, either literally or under the doctrine of equivalents.

18. An actual and justiciable controversy exists between Fresenius and Plaintiffs/Counterclaim Defendants concerning the non-infringement of the ’170 patent.

19. Fresenius is entitled to a declaratory judgment that the manufacture, use, offer for sale, sale, or importation of the Fresenius NDA Product does not and will not infringe, directly or indirectly, any valid and enforceable claim of the ’170 patent.

COUNT II
(Declaratory Judgment of Invalidity of the ’170 Patent)

20. Fresenius incorporates by reference the preceding Counterclaim paragraphs 1 to

19 as if fully set forth herein.

21. Each and every claim of the '170 patent is invalid for failure to comply with the requirements of patentability including those requirements set forth in 35 U.S.C. §§ 101 *et seq.*, including 35 U.S.C. §§ 101, 102, 103, 112 or 116, or for obviousness-type double patenting.

22. An actual and justiciable controversy exists between Fresenius and Plaintiffs concerning the invalidity of the '170 patent.

23. Fresenius is entitled to a declaratory judgment that each and every claim of the '170 patent is invalid.

COUNT III

(Declaratory Judgment of Non-Infringement of the '907 Patent by the Fresenius NDA Product)

24. Fresenius incorporates by reference the preceding Counterclaim paragraphs 1 to 23 as if fully set forth herein.

25. The manufacture, use, offer for sale, sale, or importation of the Fresenius NDA Product does not and will not infringe, directly or indirectly, any valid and enforceable claim of the '907 patent, either literally or under the doctrine of equivalents.

26. An actual and justiciable controversy exists between Fresenius and Plaintiffs concerning the non-infringement of the '907 patent.

27. Fresenius is entitled to a declaratory judgment that the manufacture, use, offer for sale, sale, or importation of the Fresenius NDA Product does not and will not infringe, directly or indirectly, any valid and enforceable claim of the '907 patent.

COUNT IV

(Declaratory Judgment of Invalidity of the '907 Patent)

28. Fresenius incorporates by reference the preceding Counterclaim paragraphs 1 to 27 as if fully set forth herein.

29. Each and every claim of the '907 patent is invalid for failure to comply with the requirements of patentability including those requirements set forth in 35 U.S.C. §§ 101 *et seq.*, including 35 U.S.C. §§ 101, 102, 103, 112 or 116, or for obviousness-type double patenting.

30. An actual and justiciable controversy exists between Fresenius and Plaintiffs concerning the invalidity of the '907 patent.

31. Fresenius is entitled to a declaratory judgment that each and every claim of the '907 patent is invalid.

PRAYER FOR RELIEF

WHEREFORE, Fresenius respectfully requests this Court enter a Declaratory Judgment and Order in its favor of Fresenius and against Plaintiffs/Counterclaim Defendants, granting the following relief:

- A. dismissing Plaintiffs' Complaint, in its entirety, with prejudice;
- B. declaring each and every claim of the '170 patent invalid;
- C. declaring each and every claim of the '907 patent invalid;
- D. declaring that Fresenius's importation, manufacture, use, offer for sale, or sale of the Fresenius NDA Product that is the subject of NDA No. 207937 does not and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contribution), any valid and enforceable claim of the '170 patent;
- E. declaring that Fresenius's importation, manufacture, use, offer for sale, or sale of the Fresenius NDA Product that is the subject of NDA No. 207937 does not and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contribution), any valid and enforceable claim of the '907 patent;
- F. enjoining Plaintiffs/Counterclaim Defendants, their officers, agents, servant,

employees, attorneys, and representatives and any successors and assigns thereof, from charging or asserting infringement of any claim of the '170 patent against Fresenius, or anyone in privity with Fresenius;

G. enjoining Plaintiffs/Counterclaim Defendants, their officers, agents, servant, employees, attorneys, and representatives and any successors and assigns thereof, from charging or asserting infringement of any claim of the '907 patent against Fresenius, or anyone in privity with Fresenius;

H. awarding Fresenius its reasonable costs (including expert fees), expenses, and attorney's fees in this action, this being an exceptional case in accordance with 35 U.S.C. § 285, among other grounds;

I. awarding Fresenius its reasonable costs and attorney's fees in defending this action; and

J. granting such other and further relief as this Court may deem just and proper.

LITE DEPALMA GREEBERG, LLC

Dated: March 17, 2015

/s/ Michael E. Patunas

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*Attorneys for Defendant
Fresenius Kabi USA, LLC*

LOCAL CIVIL RULE 11.2 CERTIFICATION

Pursuant to Local Civil Rule 11.2, I hereby certify that the matter in controversy is related to the following civil actions:

- *Sanofi-Aventis US LLC et al. v. Fresenius Kabi USA, LLC*, 14-cv-08082 (D.N.J.) (MAS) (LHG)
- *Sanofi-Aventis US LLC et al. v. BPI Labs, LLC et al.*, 14-cv-08081 (D.N.J.) (MAS) (LHG)
- *Sanofi-Aventis US LLC et al. v. Accord Healthcare, Inc.*, 14-cv-08079 (D.N.J.) (MAS) (LHG)
- *Sanofi-Aventis US LLC et al. v. Apotex Corp. et al.*, 15-cv-00287 (D.N.J.) (MAS) (LHG)
- *Sanofi-Aventis US LLC et al. v. Breckenridge Pharmaceutical, Inc.*, 15-cv-00289 (D.N.J.) (MAS) (LHG)
- *Sanofi-Aventis US LLC et al. v. Onco Therapies Limited*, 15-cv-00290 (D.N.J.) (MAS) (LHG)
- *Sanofi-Aventis US LLC et al. v. Actavis LLC et al.*, 15-cv-00776 (D.N.J.) (MAS) (LHG)
- *Sanofi-Aventis US LLC et al. v. Apotex Corp., et al.*, 15cv1835 (D.N.J.) (MAS) (LHG)
- *Sanofi-Aventis US LLC et al. v. Breckenridge Pharmaceuticals, Inc.*, 15cv1836 (D.N.J.) (MAS) (LHG)

I hereby certify that the following statements made by me are true. I am aware that if any of the foregoing statements made by me are willfully false, I am subject to punishment.

LITE DEPALMA GREEBERG, LLC

Dated: March 17, 2015

/s/ Michael E. Patunas

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*Attorneys for Defendant
Fresenius Kabi USA, LLC*

CERTIFICATE OF SERVICE

I, Michael E. Patunas, hereby certify that on this day, I served a copy of the Answer and Counterclaims of Defendant Fresenius Kabi USA, LLC on counsel for plaintiffs via the Court's ECF system and by email.

Dated: March 17, 2015

s/Michael E. Patunas

Michael E. Patunas